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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/716,314	11/18/2003	John M. Stewart	P26,473-A USA	7296

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EXAMINER	
ROOKE, AGNES BEATA	
ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 10/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/716,314	STEWART ET AL.	
	Examiner	Art Unit	
	Agnes B. Rooke	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-28* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-14, drawn to a shrew paralytic peptide, classified in class 530, subclass 350.

II. Claims 1-14, drawn to a peptide of SEQ ID NO:1 and SEQ ID NO:2, classified in class 530, subclass 350.

III. Claim 15, drawn to a method of dissociating a shrew paralytic peptide, classified in class 514, subclass 12.

IV. Claim 15, drawn to a method of dissociating SEQ ID NO:1 and SEQ ID NO:2, classified in class 514, subclass 12.

V. Claim 16-21, drawn to the use of a shrew paralytic peptide, classified in class 514, subclass 12.

VI. Claims 16-21, drawn to the use of SEQ ID NO:1 and SEQ ID NO:2.

VII. Claim 22, drawn to a method of treatment of migraine by using a shrew paralytic peptide, classified in class 514, subclass 12.

VIII. Claim 22, drawn to a method of treatment of migraine by using SEQ ID NO:1 and SEQ ID NO:2, classified in class 514, subclass 12.

IX. Claims 23 and 24, drawn to a method of providing analgesia suing a shrew paralytic peptide, classified in class 514, subclass 12.

X. Claims 23 and 24, drawn to a method of providing analgesia suing SEQ ID NO:1 and SEQ ID NO:2, classified in class 514, subclass 12.

XI. Claim 25, drawn to a method of reducing wrinkles using a shrew paralytic peptide, classified in class 514, subclass 12.

XII. Claim 25, drawn to a method of reducing wrinkles using SEQ ID NO:1 and SEQ ID NO:2, classified in class 514, subclass 12.

XIII. Claim 26, drawn to an antibody to a shrew paralytic peptide, classified in class 530, subclass 387.1.

XIV. Claim 26, drawn to an antibody to SEQ ID NO:1 and SEQ ID NO:2, classified in class 514, subclass 12.

XV. Claim 27, drawn to a method determining the potency of a paralytic agent, classified in class 514, subclass 12.

XVI. Claim 28, drawn to a nucleic acid encoding a shrew paralytic peptide, classified in class 435, subclass 69.1.

XVII. Claim 28, drawn to a nucleic acid encoding SEQ ID NO:1 and SEQ ID NO:2, classified in class 435, subclass 69.1.

The inventions are distinct, each from the other because of the following reasons:

The protein of invention I is related to the antibody of invention XIII by virtue of being the cognate antigen necessary for the production of antibodies. Although the protein and antibody are related due to the necessary steric

complementarity of the two, they are distinct inventions because the protein can be used in another and materially different process from the use for the production of the antibody, such as in a pharmaceutical composition, or to assay or purify the natural ligand of the protein, or in assays for the identification of agonists or antagonists of the receptor protein. Therefore, the inventions are distinct.

The protein of invention II is related to the antibody of invention XIV by virtue of being the cognate antigen necessary for the production of antibodies. Although the protein and antibody are related due to the necessary steric complementarity of the two, they are distinct inventions because the protein can be used in another and materially different process from the use for the production of the antibody, such as in a pharmaceutical composition, or to assay or purify the natural ligand of the protein, or in assays for the identification of agonists or antagonists of the receptor protein. Therefore, the inventions are distinct.

The protein of invention I and nucleic acid of invention XVI are patently distinct inventions for the following reasons. Proteins, which are composed of amino acids, and nucleic acids, which are composed of purine and pyrimidine units, are structurally distinct molecules. In the present invention, the nucleic acid of Invention III does not necessarily encode the proteins of Invention I. Also, the information provided by the nucleic acid of invention III can be used to make a materially different protein than that of Invention I. Moreover, the proteins of

invention I can be recovered from a natural source using biochemical means, such as affinity chromatography. Therefore, the inventions are distinct.

The protein of invention II and nucleic acid of invention XVII are patently distinct inventions for the following reasons. Proteins, which are composed of amino acids, and nucleic acids, which are composed of purine and pyrimidine units, are structurally distinct molecules. In the present invention, the nucleic acid of Invention III does not necessarily encode the proteins of Invention I. Also, the information provided by the nucleic acid of invention III can be used to make a materially different protein than that of Invention I. Moreover, the proteins of invention I can be recovered from a natural source using biochemical means, such as affinity chromatography. Therefore, the inventions are distinct.

The nucleic acid of invention XVI and the antibody of invention XIII are related by virtue of the protein that is encoded by the nucleic acid and necessary for the production of the antibody. However, the nucleic acid itself is not necessary for antibody production and both are different compounds having different compositions and functions. Therefore, the inventions are distinct.

The nucleic acid of invention XVII and the antibody of invention XIV are related by virtue of the protein that is encoded by the nucleic acid and necessary for the production of the antibody. However, the nucleic acid itself is not necessary for antibody production and both are different compounds having different compositions and functions. Therefore, the inventions are distinct.

Invention I and inventions III/V/VII/IX/XI/XV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the protein of Invention I, can be used in different methods as described in inventions III/V/VII/IX/XI/XV. Therefore, the inventions are distinct.

Invention II and inventions IV/VI/VIII/X/XII/XV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the proteins of Invention II, can be used in different methods as described in inventions IV/VI/VIII/X/XII/XV. Therefore, the inventions are distinct.

Invention XIII and inventions III-XII and XV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the antibody of Invention XIII cannot be used in methods of inventions III-XII and XV. Therefore, the inventions are distinct.

Invention XIV and inventions III-XII and XV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the antibody of Invention XIV cannot be used in methods of inventions III-XII and XV. Therefore, the inventions are distinct.

Invention XVI and inventions III-XII and XV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the nucleic acid of invention XVI cannot be used in inventions III-XII and XV. Therefore, the inventions are distinct.

Invention XVII and Inventions III-XII and XV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the nucleic acid of invention XVII cannot be used in inventions III-XII and XV. Therefore, the inventions are distinct.

Inventions III-XII and XV are related by virtue of the protein that is used in all the claimed methods. However, inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, each method is distinct from each other

because they perform distinct functions, and have different modes of operation regarding different methods of use or methods of treatment. Therefore, the inventions are distinct.

Because the inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for the examination purposes as indicated is proper.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained.

Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is advised that the reply to this requirement to be complete must include an election of the Invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Agnes Rooke whose telephone number is 571-272-2055. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR

or Public PAIR. Status information about the PAIR system, see http://pair-direct.uspto.gov. or call 866-217-9197.

AR

Karen Cochrane Carlson PhD

KAREN COCHRANE CARLSON, PH.D
PRIMARY EXAMINER